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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	22

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/875,849	Briskin et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *24-34, 37, 38, 44, 46, and 89-100* is/are pending in the application.

Of the above, claim(s) *33, 34, 37, 38, 44, 46, and 89-100* is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) *24-32* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

X See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

X Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse of Group I, claims 24-32 in Paper No. 21 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments about Butcher et al. and the cloning of primate MAdCAM-1, paragraphs 12 and 13 of this Office Action disclose prior art anticipating the claimed inventions.

The requirement is still deemed proper and made FINAL.

2. Claims 33,34,37,38,44,46,89-100 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 21.

3. Claims 24-32 are under consideration.

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. Drawings have been submitted which fail to comply with 37 CFR 1.84 (see enclosed PTO-948).

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 24-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor

had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass fusion proteins containing primate MAdCAMs from any primate as well as polymorphic or allelic variants of any primate MAdCAM. The specification discloses one amino acid sequence encoding macaque MAdCAM and two different amino acid sequences encoding human MAdCAM. With the exception of the aforementioned disclosed amino acid sequences, the skilled artisan cannot envision the detailed structure of the encompassed proteins (or fusion proteins containing said protein) and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. For example, there is no disclosure in the specification of chimp MAdCAM or baboon MAdCAM or spider monkey MAdCAM or gibbon MAdCAM or rhesus MAdCAM or polymorphic or allelic variants of said primate MADCAMS. Regarding human MAdCAM and polymorphic or allelic variants of said human MAdCAM, there is no disclosure in the specification of human MAdCAM other than that specifically encoded by the two specific amino acid sequences disclosed in the specification. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id.

at 1240. In the instant case, the specification has provided three amino acid sequences encoding human or macaque MAdCAM. The claimed inventions encompass fusion proteins containing primate MAdCAMs from any primate as well as polymorphic or allelic variants of any primate MAdCAM. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:
"The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 24-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24, 25,27 are indefinite in the recitation of "MAdCAM" because based on the definition of said term in the specification, it is unclear what said term means or encompasses. According to the specification, page 13, first paragraph, the term MAdCAM (eg. primate MAdCAM) encompasses "functional variants" of MAdCAM. According to the

specification, page 13, last paragraph, continued on page 14, such functional variants include "functional mutant proteins" and fragments having one or more amino acid deletions. Based on said definition, it appears that a MAdCAM would encompass a single amino acid found in MAdCAM (eg. all amino acids deleted except one). In addition, it is unclear what functional means in the context of "functional variant". Regarding functional mutant proteins, the definition of said term on page 14, first complete paragraph would seem to indicate that said term encompasses any sequence wherein all of the amino acids of a MAdCAM have been substituted by other amino acids. In addition, it is unclear what functional means in the context of "functional mutant proteins". Regarding the term "functional mutant" as defined in paragraph 14, second paragraph, of the specification, said term refers to an "oligopeptide which has at least one property, activity and or/function characteristic of a primate MAdCAM". However, it is unclear what this phrase means or encompasses. For example, it is unclear what property, activity and or/function actually refers to.
Claim 25 is indefinite in the recitation of "variant thereof" because it is unclear what this term means or encompasses.

10. Regarding the priority date of the instant application with regards to the application of prior art, the claimed inventions are not disclosed in parent application 08/386857 and therefore the claimed inventions are not entitled to priority to said application with regards to the application of prior art.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 24-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Butcher et al. (WO 94/13312).

Regarding the term primate MAdCAM, based on the definition of said term in the specification (as per paragraph 9 of this Office Action) , primate MAdCAM appears to encompass any molecule with one amino acid found in primate MAdCAM or any molecule that has no amino acids in common with MAdCAM, or any molecule with one property, activity and or/function characteristic of a primate MAdCAM. Butcher et al. teach MAdCAM/Ig constant region fusion proteins (see page 7). Murine MAdCAM would be a "primate MAdCAM" as this term is defined in the specification because it has one amino acid in common with the actual species of primate MAdCAM disclosed in the specification. In addition, it also qualifies as a "primate MAdCAM" because it has numerous properties, activities and functional characteristics of naturally occurring human MAdCAM (eg. both made of amino acids, both mediate adhesion, both found in mammals, both contain carbon and oxygen molecules, etc). Butcher et al. teach that the peptide is joined to IgG, indicating that the c-terminal of said peptide is joined to the N-terminal of Ig (see page 7). Butcher et al. teach soluble MAdCAM (page 5) and fusion molecules containing said peptide (see page 7). The MAdCAM/Ig fusion protein taught by Butcher et al. contains at least a portion of Ig heavy chain constant region (eg. intact IgG, see page 7). It is an inherent property of IgG that it contains hinge, CH2 and CH3 domains because these regions are found in IgG. The fusion protein taught by Butcher et al. is a "hybrid immunoglobulin".

13. Claims 24-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Capon et al. (US Patent 5,565,335).

Regarding the term primate MAdCAM, based on the definition of said term in the specification (as per paragraph 9 of this Office Action) , primate MAdCAM appears to encompass any molecule with one amino acid found in primate MAdCAM or any molecule that has no amino acids in common with MAdCAM, or any molecule with one property, activity and or/function characteristic of a primate MAdCAM. Capon et al. teach immunoadhesion fusion proteins (see claims 1-14). The various adhesion molecules taught by Capon et al. would be "primate MAdCAM" as this term is defined in the specification because they have one amino acid in common with the actual species of primate MAdCAM disclosed in the specification. In addition, they would also qualify as a "primate MAdCAM" because they have numerous properties, activities and functional

characteristics of naturally occurring human MAdCAM (eg. both made of amino acids, both mediate adhesion, both found in humans, both contain carbon and oxygen molecules, etc). Capon et al. teach the claimed fusion proteins (see claims 1-14 and Examples).

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1640 at (703) 305-3014.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1640

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
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